UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,433	11/16/2001	Sikander Randhava	13909-00002	6093

7590 02/27/2003

KATTEN MUCHIN ZAVIS
Attention : Patent Administrator
Suite 1600
525 West Monroe Street
Chicago, IL 60661-3693

EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/992,433	Randhava et al.
Examiner	**Art Unit**
Christopher Tate	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 21, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-23* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election of Group I, claims 1-23, in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-23 are presented for examination on the merits.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 8, 11, 14, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 8, 14, and 20 are rendered vague and indefinite by the Markush recitation "by a method selected from the group consisting of microencapsulation ...; and capsulation ...; and binding ...". It is suggested that the term "and" preceding the word "capsulation" be deleted from this phrase so as to clarify what is being define by the overall Markush grouping.

Claim 11 is rendered vague and indefinite because it is not clear from the body of this Jepsen claim if the improved composition actually contains saw palmetto extract therein.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1-3, 6-8, and 11-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Mann (US 6,231,866).

An oral composition for treating benign prostatic hyperplasia (BPH) comprising saw palmetto extract and a controlled release system comprising a coating formed from a material impervious to acidic conditions in the stomach that is soluble in the duodenum and small intestines is claimed as well as a method of treating BPH using such a composition.

Mann teaches a controlled release composition comprising saw palmetto extract (termed SAW-MAX) useful for treating BPH, including formulating the composition into a capsule (thus capsulation) which coats/shields the internal bioactive agent from stomach acid degradation so as to release a maximum concentration of bioactive agent to the intestines (see entire document including col 2, lines 3-61; col 5, lines 40-67; col 8, lines 38-49; col 9, line 14 - col 10, line 33).

The controlled release composition taught by Mann would inherently initially release saw palmetto extract in the duodenum and before it enters the colon.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-3, 6-8, 11, 18-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Wilding (US 2001/0008638).

Wilding teaches a controlled release composition (including capsules) comprising saw palmetto extract that comprises two or more enteric coatings, whereby the controlled release formulation may be one of numerous prior art controlled release formulations (see, e.g., page 2, paragraphs 0016-0023) including some which would inherently withstand stomach acid degradation and allow release of the saw palmetto extract into the duodenum before entering the colon.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding (US 2001/0008638) or Mann (US 6,231,866), in view of Locke (US 6,200,573) and Acharya (US 5,102,666).

Wilding and Mann are relied upon for the reasons discussed *supra*. In addition, although Wilding does not expressly teach treating BPH via administering the controlled release formulation containing saw palmetto extract, Wilding discloses that the saw palmetto extract is an anti-estrogen ingredient which is useful for treating BPH by decreasing the conversion of testosterone to DHT (see, e.g., page 1, paragraphs 0007- 0008). Further, although Mann does not expressly teach encapsulating the SAW-MAX preparation within an enteric-type coating, Mann does disclose that the SAW-MAX controlled release formulation may optionally be encapsulated (see, e.g., col 10, lines 30-33). Neither of the primary references expressly teach the inclusion of a compound which minimizes (inhibits) smooth muscle contraction - such as peppermint.

Locke beneficially teaches treating BPH via oral administration of a composition (including a capsule) comprising saw palmetto extract and an alpha-adrenergic antagonist compound which inhibits (minimizes) prostatic smooth muscle contraction - i.e., relaxes the prostatic smooth muscle. Locke also beneficially teaches that the composition can be formulated into a once-a-day or even longer sustained release composition using conventional techniques well known in the art (see, e.g., abstract; col 2, lines 4-22; col 3, lines 25-44; col 5, lines 27-42; col 7, line 55 - col 8, line 3; col 9, lines 23-35; and claims).

Acharya beneficially teaches the inclusion of peppermint oil as a flavoring agent to controlled release pharmaceutical formulations including capsules (see, e.g., col 8, lines 6-16).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer one or more of the controlled-release saw palmetto extract-containing compositions taught by either of the primary references to a patient suffering from BPH based upon the beneficially teaching provided therein. It would also have been obvious to one of ordinary skill in the art to further include a compound which inhibits smooth muscle contraction therein based upon the beneficial teachings provided by Locke, and/or to include peppermint as a well known flavoring agent therein based upon the beneficial teachings provided by Acharya (please note that peppermint flavoring would intrinsically provide the functional effect instantly claimed). The adjustment of particular conventional working conditions (e.g., coating the SAW-MAX formulation of Mann with a conventional enteric coating or other controlled release-type coating; and/or determining a result-effective prior art controlled release formulation in which to incorporate the cited saw palmetto extract compositions so as to effectively release the saw palmetto extracts into the duodenum/small intestines - especially given that Wilding clearly indicates that various types of prior art controlled release formulation technologies can be used to accomplish this controlled-release feature) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jia (US 2002/0071869), in view of Mann (US 6,231,866), Wilding (US 2001/0008638), and Locke (US 6,200,573), and further in view of Acharya (US 5,102,666).

The Mann and Wilding references are relied upon for the reasons discussed *supra*.

Jia teaches the incorporation of a biologically active agent such as saw palmetto extract within a bioadhesive preparation so as to protect and target the delivery of the bioactive agent to target cells. Jia also discloses that the bioadhesive composition can be formulated within time-release capsules (see, e.g., pages 1-2, paragraph 0007-0008 and 0018; page 4, paragraphs 0034-0035; and claims).

Locke beneficially teaches treating BPH via oral administration of a composition (including a capsule) comprising saw palmetto extract and an alpha-adrenergic antagonist compound which inhibits (minimizes) prostatic smooth muscle contraction- i.e., relaxes the prostatic smooth muscle. Locke also beneficially teaches that the composition can be formulated into a once-a-day or even longer sustained release composition using conventional techniques

well known in the art (see, e.g., abstract; col 2, lines 4-22; col 3, lines 25-44; col 5, lines 27-42; col 7, line 55 - col 8, line 3; col 9, lines 23-35; and claims).

Acharya beneficially teaches the inclusion of peppermint oil as a flavoring agent to controlled release pharmaceutical formulations including capsules (see, e.g., col 8, lines 6-16).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the bioadhesive saw palmetto extract preparation of Jia within a time-release/controlled-release formulation and to treat BPH using such a formulation based upon the beneficial teaching provided by Mann, Wilding, and Locke, with respect to time-release/controlled release saw palmetto extract formulations useful for treating BPH.

It would further have been obvious to one of ordinary skill in the art to further include a compound which inhibits smooth muscle contraction therein based upon the beneficial teachings provided by Locke, and/or to include peppermint as a well known flavoring agent therein based upon the beneficial teachings provided by Acharya (please note that peppermint flavoring would intrinsically provide the functional effect instantly claimed). The adjustment of particular conventional working conditions (e.g., coating the bioadhesive formulation taught by Jia with a conventional enteric coating or other time-release/controlled release-type coating; and/or determining a result-effective prior art controlled release formulation in which to incorporate the cited saw palmetto extract compositions so as to effectively release the saw palmetto extracts into the duodenum/small intestines - especially given that Wilding clearly indicates that various types of prior art controlled release formulation technologies can be used to accomplish this controlled-

release feature) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

Christopher R. Tate
Primary Examiner, Group 1654